



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/774,232 | 01/30/2001 | Said Saim | 9/186 | 1125 |

23703 7590 03/18/2004

BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P O BOX 368
RIDGEFIELD, CT 06877

EXAMINER

KUMAR, SHAILENDRA

ART UNIT PAPER NUMBER

1621

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/774,232 | SAIM ET AL. | |
| | Examiner | Art Unit | |
| | SHAIENDRA - KUMAR | 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/16/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-26 are pending in this application.

1. ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11 and 22-26, drawn to a process of preparing a drug compound, classified in class 564, subclass 192+.
- II. Claims 12-17, drawn to a method of coating, classified in class 427, subclass 2.1+.
- III. Claims 18-21, drawn to a cleaning method, classified in class 134, and /or class 8.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as used together and have different operation, functions, and effects. Invention I is a method of making and purifying a chemical compound, such as acetaminophen (page 29 of the instant specification). Invention II is a method of coating. Invention III is a method of cleaning, all unrelated.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Phil Datlow on 7/4/2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-11 and 22-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-11 and 22-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

Art Unit: 1621

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims are directed to a method of processing a solute, by dissolving in a liquid, and then dissolving a gas etc. It is not clear as to what solute, what solvent and what gas is contemplated in herein. There is but one example, acetaminophen in the instant specification, but it is not clear whether, the same process can be carried out with any other solvent and adding gas therein. For example, acetaminophen can be solubilized in acetone, dimethylformamide, ethylene dichloride, ethyl acetate, hot water and even to some extent in ether. The specification is not enabled for any of the listed solvent. The same can be said for gaseous fluid. For example, the specification is not enabled for nitrogen.

9. Claims 1-11 and 22-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for acetaminophen and ethanol as solvent, does not reasonably provide enablement for tetracycline or penicillin, or glucophage, or aspirin etc, and for any other solvent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. For example, acetaminophen can be solubilized in acetone, dimethylformamide, ethylene dichloride, ethyl acetate, hot water and even to some extent in ether. The specification is not enabled for any of the listed solvent. The same can be said for gaseous fluid. For example, the specification is not enabled for nitrogen. There are other gaseous fluid, not enabled as well, for example oxygen, hydrogen etc.

Art Unit: 1621

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-11 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of Hanna et al(US 6,063,138) and Smith(US 4,582,731).

Instant claims are directed to a method of processing a solute, by dissolving in a liquid solvent, and then dissolving a gaseous fluid, then expanding the solute/solvent/gaseous fluid phase, followed by other steps claimed in claim 1.

Hanna et al is teaching method of formation of particles, by dissolving the solute in a liquid, and adding gaseous fluid, see the abstract. The difference between the reference and herein claimed process is that the reference fails to mention the expansion of the trio phase.

Smith et al is teaching deposition of solid film, in which it is expressly taught that the media can be expanded at will, see the abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Hanna et al, by including the steps of expansion of the trio phase, as taught by Smith et al, because the latter reference is expressly teaching the advantage of the expansion step, with the reasonable expectation of achieving a precipitated solute, absent evidence to the contrary. As regards to the rest of the steps (d) to (g) of the claims, it was well within the ordinary skill in the art to vary the pressure, temperature etc, under routine experimentation.

No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

Art Unit: 1621

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAIENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
3/16/04